

PediFrag™ System 2.7mm/3.5mm

SURGICAL TECHNIQUE



TABLE OF CONTENTS

System Overview

Indications	4
Plates	5
Screws	6

Surgical Technique

Fixation Principles	7
Plate Fixation.....	9
Plate Selection & Contouring	9
Reduction & Plate Placement	10
Cortical Screw Insertion (neutral).....	11
Cortical Screw Insertion (compression).....	13
Locking Screw Insertion.....	17
Lag Screw Fixation	18
Cannulated Screw Fixation	20
Condylar Pinning.....	22

Product Information

Plates	24
Screws	26
Instruments	28

INDICATIONS

The OrthoPediatrics PediLoc® Fragment System is intended to provide temporary internal fixation and stabilization of long bones, short (small) bones, pelvis, and scapula. This includes fractures, osteotomies, mal-unions, and non-unions in all pediatric subgroups (except neonates), and small stature adults.

Description:

The OrthoPediatrics PediFrag™ System 2.7/3.5 is part of the PediLoc® Product Family and includes plates and screws used for internal fixation to facilitate bone healing and repair. It combines the advantages of traditional plating techniques with the advancements offered by locked plating.

This flexible system includes plates that can be used with 2.7mm and 3.5mm cortical and locking screws, as well as 4.0mm cannulated cancellous screws. System components are manufactured from stainless steel for increased strength and ease of removal.

Contents of the system include:

- 2.7mm locking compression plates
- 1/4 tubular plates and reconstruction plates
- 3.5mm locking compression plates
- 1/3 tubular plates
- Reconstruction plates
- Locking T-plates
- 4.0mm partial and fully threaded screws

Within this system, size identification is aided by colors:

- Yellow - 2.7mm instruments and implants
- Blue - 3.5mm instruments and implants

PLATES

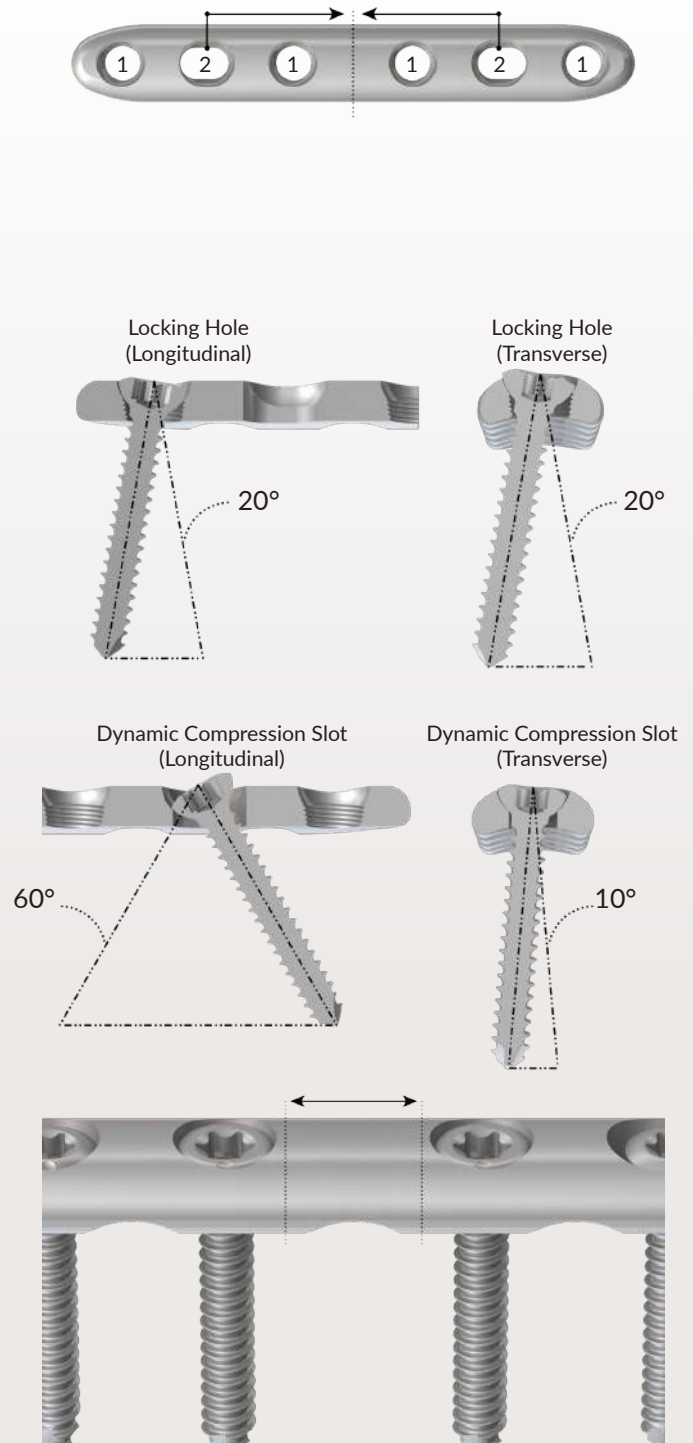
The PediFrag Fragment plates contain two types of holes: locking (1) and dynamic compression (2), shown to the right.

Starting from the center of the plate and moving outward, the holes alternate between locking and dynamic compression. The dynamic compression slots are oriented so that compression is directed toward the center of the plate.

The locking holes allow for insertion of locking, cortical, and cancellous screws. Using cortical and cancellous screws, 20° of angulation can be obtained in both the longitudinal and transverse planes.

The dynamic compression slots allow for insertion of cortical screws and cancellous screws with the ability to obtain 60° of longitudinal angulation and 10° of transverse angulation. Maximum achievable compression per dynamic compression slot is 1.5mm.

In addition, the plates (excluding tubular plates) have increased distance between the middle two locking holes. This allows room for overlapping the fracture/osteotomy site while preserving the use of the first locking hole.

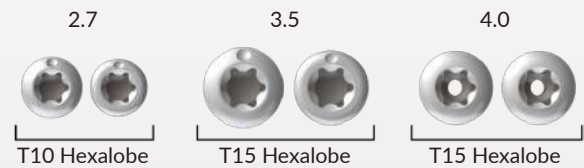
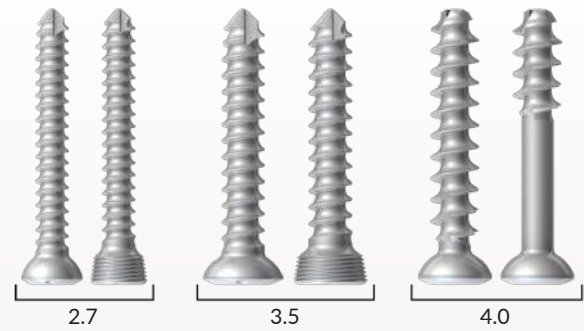


SCREWS

The PediFrag system contains locking, cortical, and cannulated cancellous screws. All screws are self-tapping.

The locking and cortical screws are available in 2.7mm and 3.5mm diameters. The diameter of the cannulated cancellous screws is 4.0mm. The 2.7mm screws use a T10 Hexalobe Driver, while the 3.5mm and 4.0mm screws use a T15 Hexalobe Driver.

The locking screws use triple lead threads, which facilitate efficient engagement of the locking screw into the locking hole.

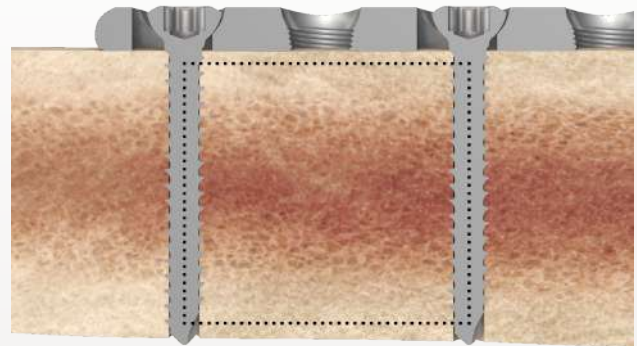


FIXATION PRINCIPLES

Anatomic reduction, stable fixation, preservation of blood supply, and early active mobilization are key principles in successful internal fixation.

Bicortical Screw/Plate Fixation

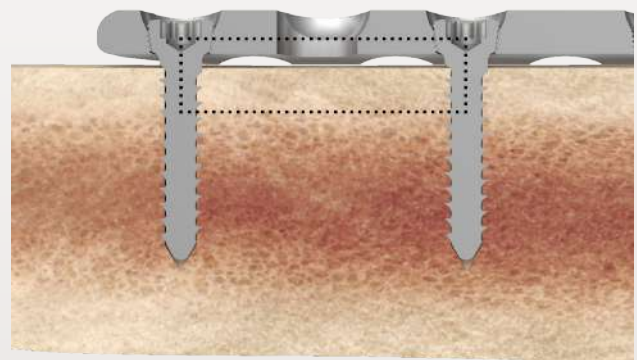
Cortical screw insertion achieves compression of the plate to the surface of the bone. This compression creates frictional resistance for stability of constructs during rehabilitation. This requires the cortical screw to be fixed/inserted in two cortices, known as bicortical fixation.



Bicortical

Unicortical Screw/Plate Fixation

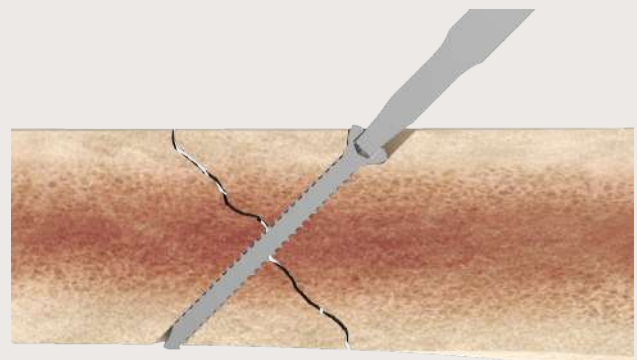
Locking screw insertion provides stability utilizing locking threads to create a fixed point within the plate construct. Plate/bone compression is not required to create frictional resistance for stability. This requires the locking screw to pass through, at minimum, the near cortex.



Unicortical (Locking)

Lag Screw Fixation

Lag screw fixation provides stability by inserting screws across the fracture plane. Inter-fragmentary compression is created by over-drilling the near cortex, or utilizing partially threaded screws in which the opposing fragment is pulled towards the near fragment.



FIXATION PRINCIPLES

Dynamic compression requires fixation of the opposing fragment first.

Step 1

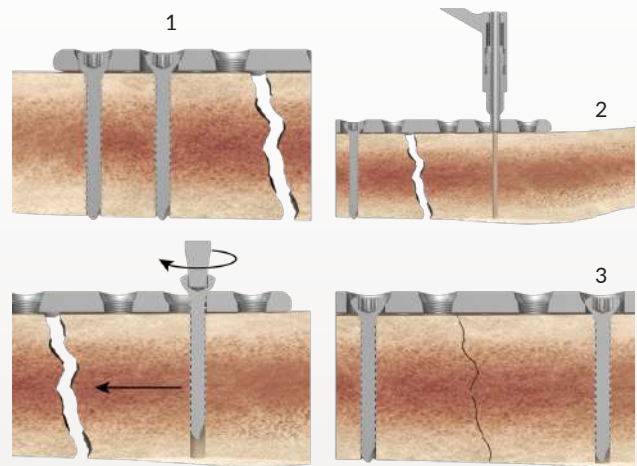
Insert screws, locking or cortical, into the bone segment opposite of the bone segment being compressed.

Step 2

Drill eccentrically with the universal drill guide in the bone segment being compressed.

Step 3

Insert cortical screw in compression slot and achieve compression.



Dynamic Compression Plating

The combination of cortical, locking and lag screw fixation with dynamic compression allows for anatomical corrections of multiple types of fractures and osteotomies.

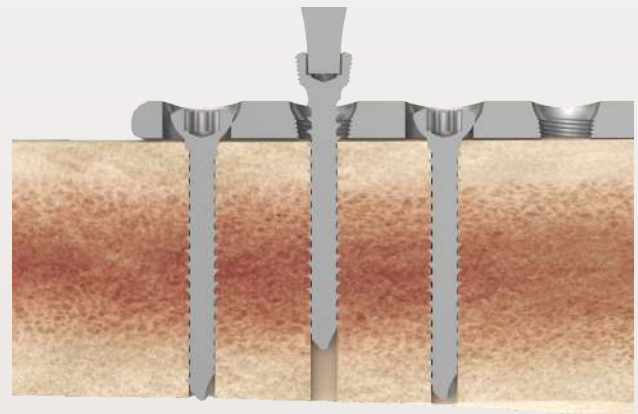


PLATE FIXATION

1

Plate Selection & Contouring

Select a plate that allows for two to three usable holes on each side of the fracture. Using the bending template and bending irons, select the appropriate plate and contour to fit the anatomy. If necessary, contour the bending templates to the appropriate anatomical shape (Figures 1a - 1c).

- 1 *Note: Bending plates through locking holes can cause significant distortion of the locking threads making locking screw insertion difficult. Threaded drill guides and threaded plate holders can be used to protect threads.*
- 2 *Note: Due to fatigue, plates will not withstand bending multiple times in one location. If damage occurs, do not use implant.*
- 3 *Note: While bending the plates, bending pliers may be used to maintain control of the implant.*

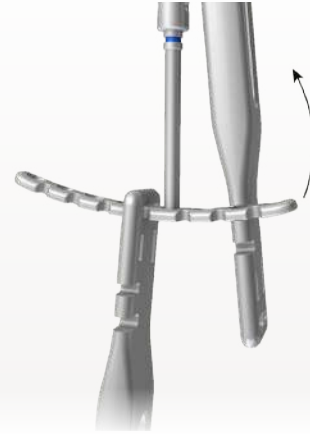


FIGURE 1a: Contour plate

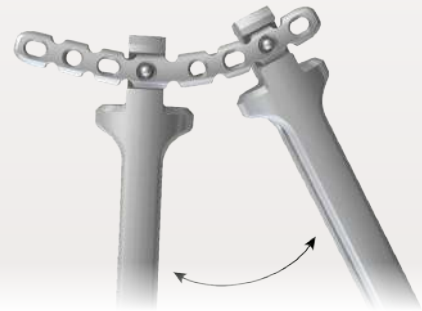


FIGURE 1b: Contour plate

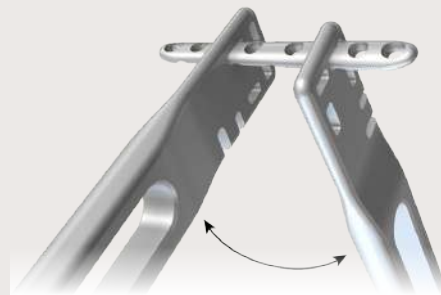


FIGURE 1c: Contour plate

2

Reduction & Plate Placement

Use the plate fixation pin and/or Verbrugge forceps to temporarily attach the plate to the bone (Figure 2).

- 1 Note: Plate provisional fixation pins **should not** be used with 2.7mm plates and screws, as the plate fixation screw shaft is larger than the drill hole.
- 2 Note: Pointed reduction forceps, toothed reduction forceps, and sharp hooks are available to assist with reduction but must be requested in addition to the PediFrag system.

Threaded plate holders and threaded drill guides can be used as handles, while simultaneously allowing for the insertion of guide wires or calibrated drill bits (Figure 3).

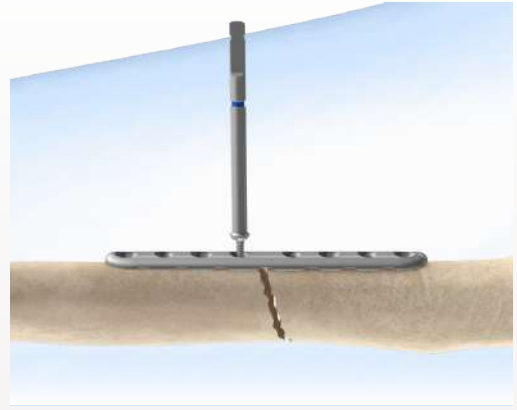


FIGURE 2: Temporarily attach plate

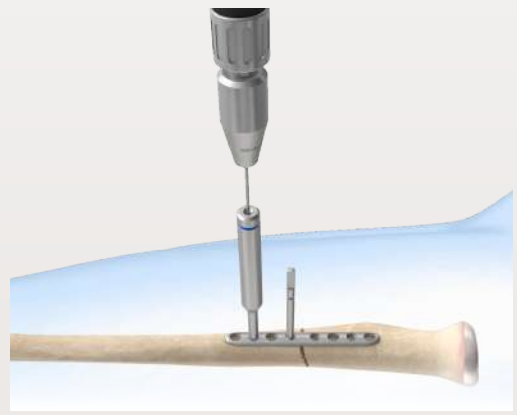


FIGURE 3: Insert guide wires or drill bits

3

Cortical Screw Insertion (neutral)

Select a compression slot or a locking hole and drill using the appropriate size drill (Figure 4).

Using the universal drill guide, select a hole in the plate and drill for a non-locking cortical screw with the appropriate size drill.

- 1 *Note: Some universal drill guides may not be spring loaded; therefore, the plunger must be reset manually.*

Insert the drill bit into the plunger on the universal drill guide and drill both cortices.

- 2 *Note: If the drill bit is too short, use an appropriate size calibrated drill bit. Do not use calibration lines for measuring, as they should be used for locking screws only. If necessary, use fluoroscopy to assist in drill depth.*
- 3 *Note: As an option, tap both cortices using the cortical taps and mini T-handle AO, QC.*

Insert the scale into the depth gauge so that the wire protrudes out of the depth gauge nose (Figure 5).

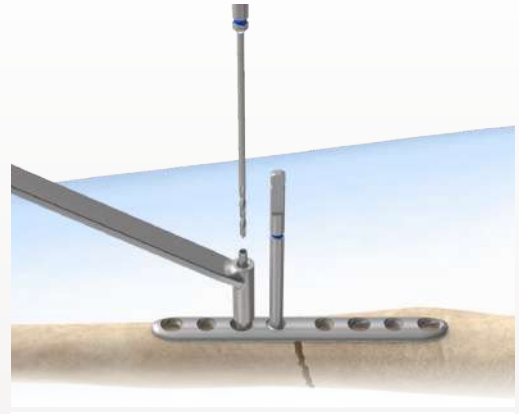


FIGURE 4: Drill for non-locking cortical screw



FIGURE 5: Assemble depth gauge

Insert the tip of the depth gauge into the pre-drilled hole and hook the far cortex (Figure 6). Slide the depth gauge down to the plate hole and read the measurement from the scale.

- 4 *Note: The nose of the depth gauge will not fit through the plate. The depth gauge and scale can come apart, so ensure components are not used inappropriately and dropped on the floor.*
- 5 *Note: All measurements are to be read from the back of the depth gauge.*

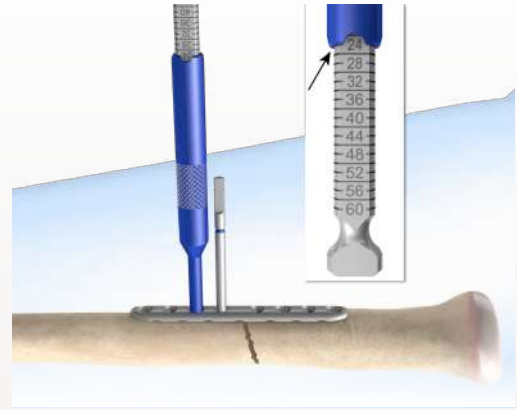


FIGURE 6: Measure for screw length after hooking far cortex

Affix the Hexalobe driver to the mini inline ratchet, confirming that the engagement position is in forward or neutral. Identify the appropriate length of screw and insert (Figure 7).

- 6 *Note: Use fluoroscopy to confirm the screw length, if the screw is not the desired length remove and replace.*

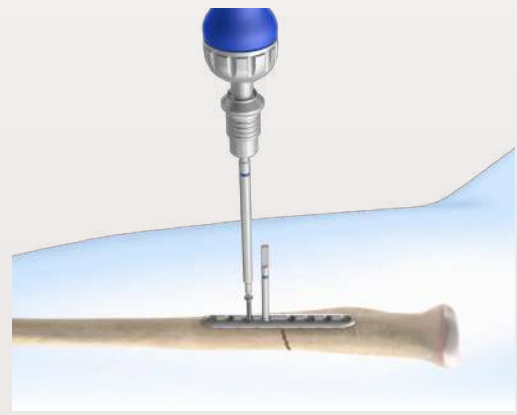


FIGURE 7: Insert screw

4

Cortical Screw Insertion (compression)

Locate the dynamic compression slot (Figure 8).

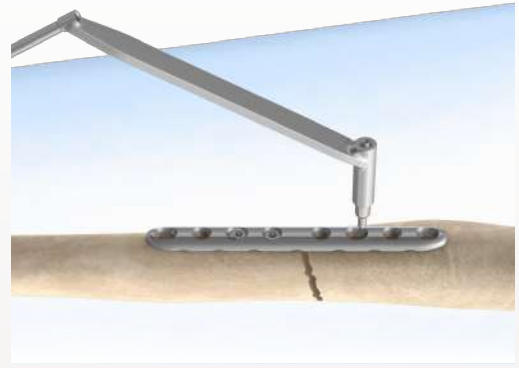


FIGURE 8: Locate compression slot

Insert the drill bit into the plunger on the universal drill guide and drill both cortices (Figure 9).

- 1 *Note: If the drill bit is too short, use an appropriate size calibrated drill bit. Do not use calibration lines for measuring, as they should be used for locking screws only. If necessary, use fluoroscopy to assist in drill depth.*
- 2 *Note: As an option, tap both cortices using the cortical taps and mini T-handle AO, QC.*

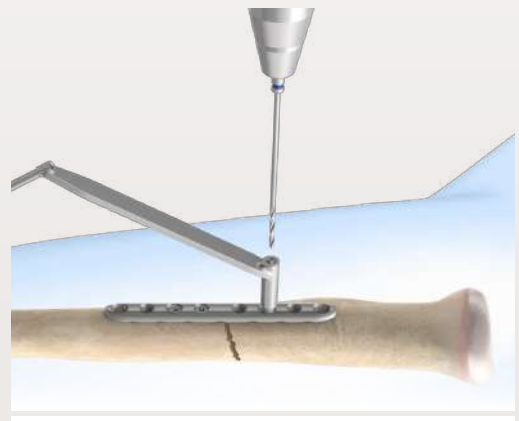


FIGURE 9: Drill both cortices

Assemble depth gauge (Figure 5).

Insert the tip of the depth gauge into the pre-drilled hole and hook the far cortex. Slide the depth gauge down to the plate hole and read the measurement from the scale (Figure 10).

- 3 *Note: The nose of the depth gauge will not fit through the plate. The depth gauge and scale can come apart, so ensure components are not used inappropriately and dropped on the floor.*
- 4 *Note: All measurements are to be read from the back of the depth gauge.*

Affix the Hexalobe driver to the mini inline ratchet confirming that the engagement position is in forward or neutral. Identify the appropriate length of screw and insert (Figure 11).

- 5 *Note: Use fluoroscopy to confirm the screw length. If the screw is not the desired length, remove and replace.*
- 6 *Note: Because the depth gauge does not fit through the plate, the dynamic compression slot could cause the cortical screw to protrude ~1.0 to 1.5mm farther than expected past the cortex.*

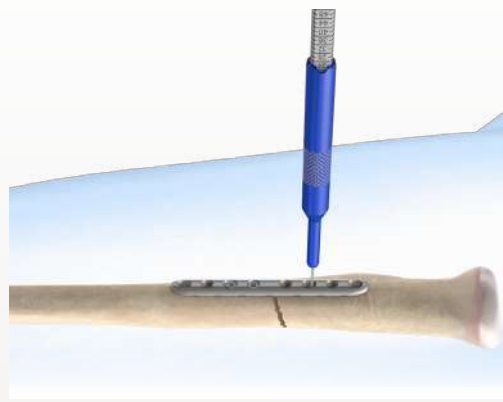


FIGURE 10: Measure for screw length after hooking far cortex

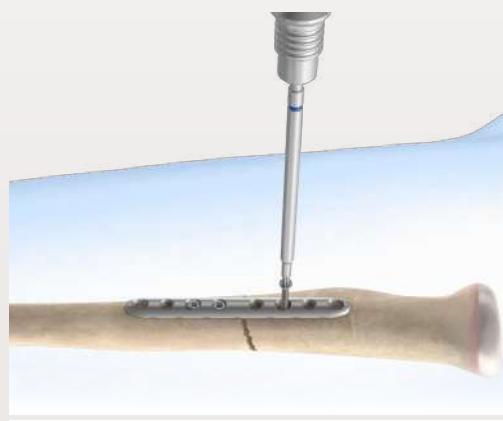


FIGURE 11: Insert screw

Dynamic Compression Mechanism

The dynamic compression mechanism will cause the bone segment to shift axially as the screw is tightened.

By placing the drill eccentrically in the hole, as depicted in the illustrations to the right, the screw head will slide down the end of the plate hole, causing the bone to shift axially (Figures 12a - 12c).

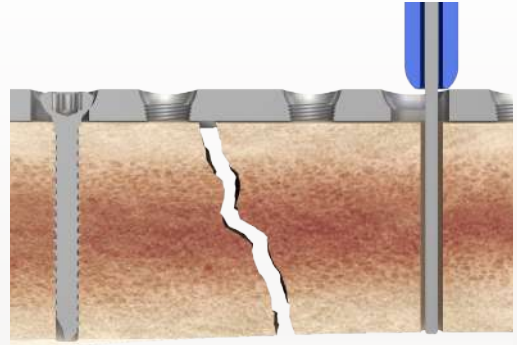


FIGURE 12a: Place drill eccentrically

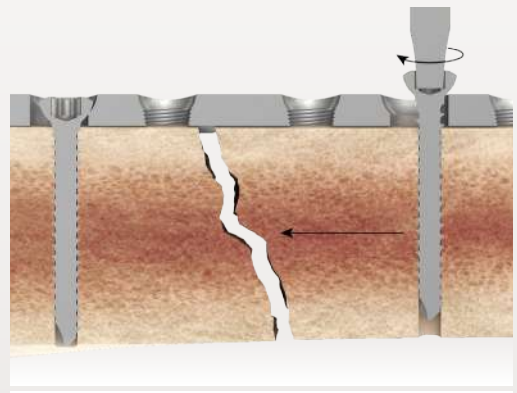


FIGURE 12b: Tighten screw to shift fragment

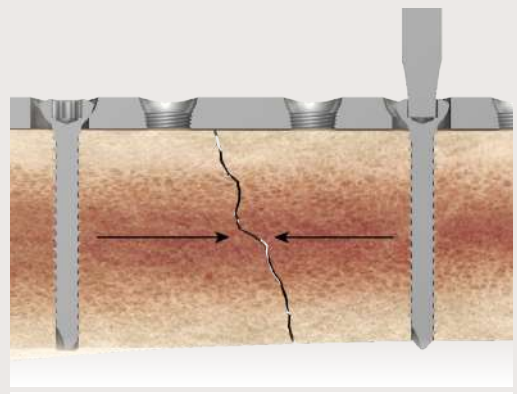


FIGURE 12c: Continue tightening until fragment is closed

5

Locking Screw Insertion

Insert the threaded drill guide into the locking hole. Be careful not to cross thread (Figure 13).

If it is difficult to engage the threaded drill guide in the plate hole, try turning the drill guide counterclockwise to align the threads. An audible clicking sound will be heard when the threads are aligned to allow the guide to be turned in a clockwise direction.

Insert the appropriate calibrated drill bit into the threaded drill guide. Drill the near cortex and continue until drill bit comes in contact with the far cortex (Figure 14). If necessary, use fluoroscopy to assist in drill depth.

Read the measurement from the calibrated drill bit from the back of the threaded drill guide and drill just past the far cortex. Alternatively, remove the threaded drill guide and use the depth gauge to measure the screw length.

- 1 *Note: It is usually not necessary, as the screws are self-tapping, but as an option, tap both cortices using the cortical taps and mini T-handle AO, QC.*

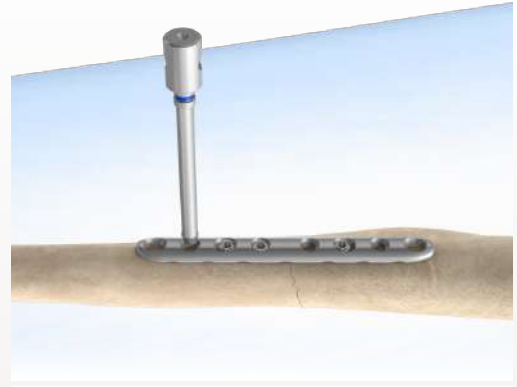


FIGURE 13: Insert threaded drill guide into locking hole

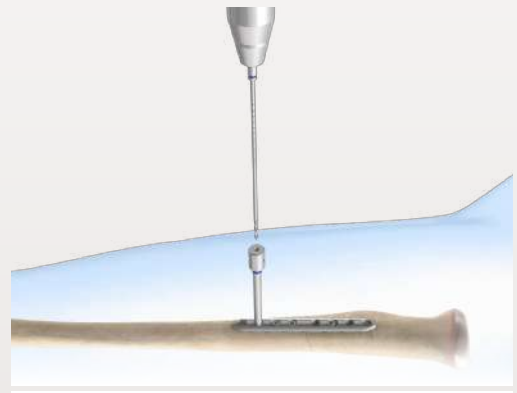


FIGURE 14: Drill until contact is made with far cortex

Affix the Hexalobe driver to mini inline ratchet confirming that the engagement position is in forward or neutral. Identify the appropriate length screw and insert (Figure 15).

- ② *Note: Use fluoroscopy to confirm the screw length. If the screw is not the desired length, remove and replace.*
- ③ *Note: Use the locking screw last if compression or cortical screw insertion is needed within the same fragment.*



FIGURE 15: Insert screw

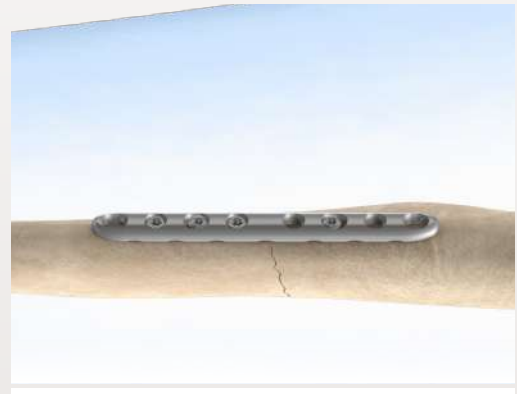


FIGURE 16: Final result

LAG SCREW FIXATION

Lag Screw Technique

2.7mm Cortex Screw Lag Screw Insertion:

- 2.7mm Drill Bit - Gliding Hole
- 2.0mm Drill Bit - Threaded Hole

3.5mm Cortex Screw Lag Screw Insertion:

- 3.5mm Drill Bit - Gliding Hole
- 2.5mm Drill Bit - Threaded Hole

Select the appropriate sized drill guide for lag screw placement (Figure 17). For a 2.7mm lag screw, use the 2.0/2.7mm Double Drill Sleeve. For a 3.5mm lag screw, use the 2.5/3.5mm Double Drill Sleeve.

For a 2.7mm lag screw, insert the 2.7mm drill bit through the 2.7mm portion of the drill guide. Align the drill bit and drill guide perpendicular to the fracture or osteotomy site. Drill through the near cortex and past the fracture/osteotomy site but NOT through the opposing bone segment or far cortex (Figure 18).

Remove the 2.7mm drill bit from the bone and switch to the opposite end of the 2.0/2.7mm Double Drill Guide. Insert the 2.0mm portion of the 2.0/2.7mm Double Drill Guide into the previously drilled hole and push it down to the opposite fragment. Switch to the 2.0mm drill bit and drill through the previously inserted drill guide through the opposing bone segment or far cortex (Figure 19).

- 1 Note: For a 3.5mm lag screw, follow the previous steps using the appropriate end of the 2.5/3.5mm Double Drill Sleeve.
- 2 Note: To avoid compromising screw purchase, do not drill into the far cortex with a larger diameter drill. If necessary, use fluoroscopy to assist in drill depth.
- 3 Note: As an option, tap the far cortex using the cortical taps and mini T-handle AO, QC.
- 4 Note: As an option, a countersink can be used to sink the screw head below the surface of the bone. Measuring must take place after the countersinking step.

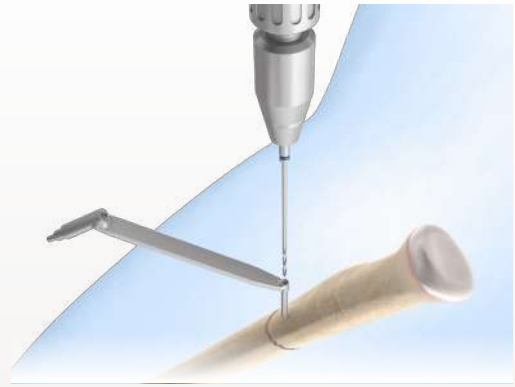


FIGURE 17: Select appropriate drill guide

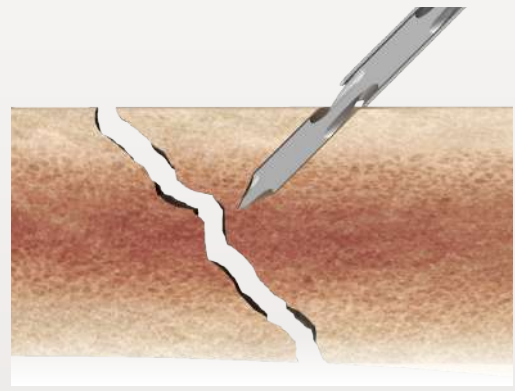


FIGURE 18: Align drill perpendicular and drill to fracture site



FIGURE 19: Drill through drill guide, passing through opposing bone segment

Insert the tip of the depth gauge into the drilled hole and hook the far cortex. Slide the depth gauge down to the bone and read the measurement from the scale (Figure 20).

- 5 *Note: The depth gauge and scale can come apart, so ensure that the components are not used inappropriately and dropped on the floor.*
- 6 *Note: All measurements are to be read from the back of the depth gauge.*
- 7 *Note: If countersinking is desired, measure after countersinking.*

Affix the Hexalobe driver to the mini inline ratchet, confirming that the engagement position is in forward or neutral. Identify the appropriate length of screw and insert (Figure 21).

- 8 *Note: Use fluoroscopy to confirm the screw length. If the screw is not the desired length, remove and replace.*
- 9 *Note: Alternatively, a lag screw can be inserted through the plate. Follow the steps above to complete if desired.*

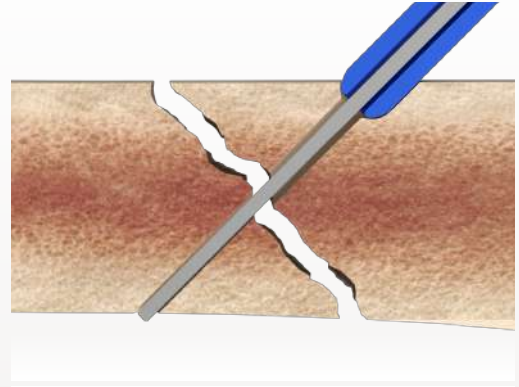


FIGURE 20: Measure for screw length after hooking far cortex

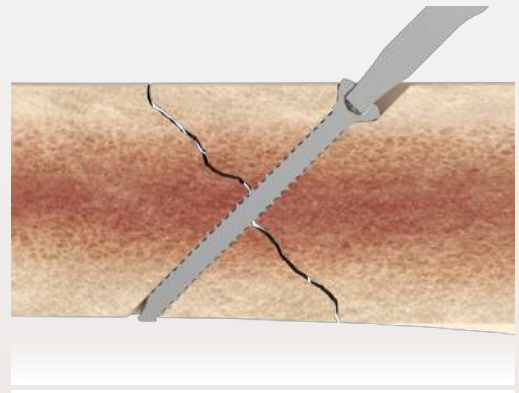


FIGURE 21: Insert screw

CANNULATED SCREW FIXATION

Insert the 1.25mm guide wire through the drill guide (1.25 side) to the desired depth. Alternatively, the wire can be inserted using a free-hand technique (Figure 22).

- 1 *Note: If inter-fragmentary compression is desired, ensure that all screw threads are past the fracture site.*



FIGURE 22: Insert 1.25mm guide wire

Insert the direct measuring device over the guide wire and read the guide wire length (Figure 23).

- 2 *Note: If countersinking is desired, measure after countersinking.*



FIGURE 23: Insert direct measuring device over guide wire

Using a 2.7mm cannulated bit, drill over the guide wire to the desired depth (Figure 24). The surgeon may use the drill guide for tissue protection.

- 3 *Note: As an option, a tap is provided for use if dense cortical bone is encountered.*



FIGURE 24: Drill over guide wire using 2.7mm cannulated drill bit

Affix cannulated Hexalobe driver to mini inline ratchet, confirming that the engagement position is in forward or neutral. Identify appropriate length of screw and insert (Figure 25).

- 4 *Note: If a washer is desired, ensure the washer is placed over the guide wire prior to screw placement.*

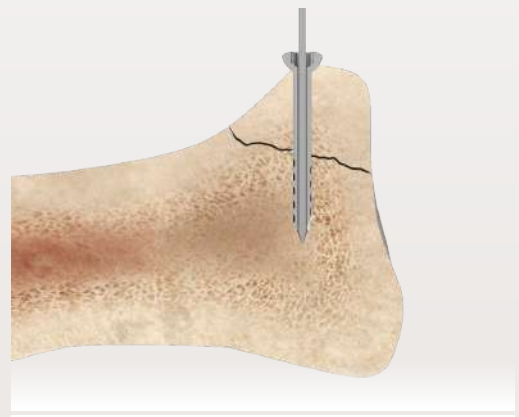


FIGURE 25: Insert screw

CONDYLAR PINNING

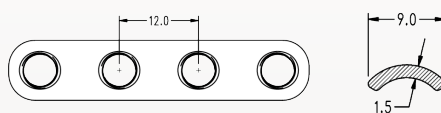
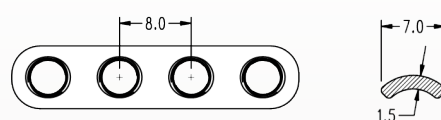
Use the 2.0 Drill Guide/Sleeve, K-Wire Bender, and Bending Iron for Wires to facilitate 1.25mm or 1.6mm smooth wire insertion.

- ① *Note: Do not use 2.0/2.5mm threaded guide wires for condylar pinning.*
- ② *Note: Use fluoroscopy to assist in wire placement.*

PLATES

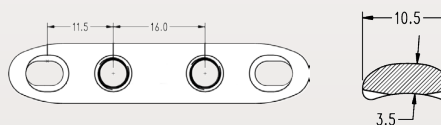
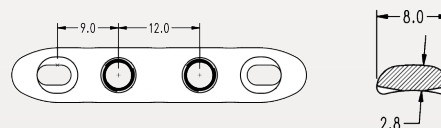
TUBULAR PLATES

Item Number	Description	Holes	Length (mm)
00-1005-2004	2.7mm 1/4 Tubular Plate	4	32
00-1005-2006	2.7mm 1/4 Tubular Plate	6	48
00-1005-2008	2.7mm 1/4 Tubular Plate	8	64
00-1005-3004	3.5mm 1/3 Tubular Plate	4	46
00-1005-3006	3.5mm 1/3 Tubular Plate	6	70
00-1005-3008	3.5mm 1/3 Tubular Plate	8	94



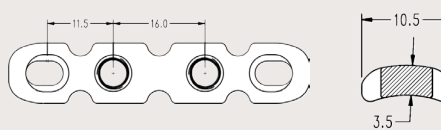
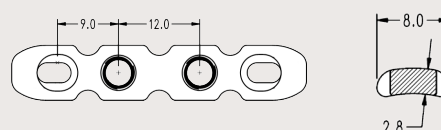
LOCKING COMPRESSION PLATES

Item Number	Description	Holes	Length (mm)
00-1005-2104	2.7mm Locking Compression Plate	4	44
00-1005-2105	2.7mm Locking Compression Plate	5	53
00-1005-2106	2.7mm Locking Compression Plate	6	62
00-1005-2108	2.7mm Locking Compression Plate	8	80
00-1005-3104	3.5mm Locking Compression Plate	4	53
00-1005-3105	3.5mm Locking Compression Plate	5	64
00-1005-3106	3.5mm Locking Compression Plate	6	76
00-1005-3108	3.5mm Locking Compression Plate	8	99
00-1005-3110	3.5mm Locking Compression Plate	10	122



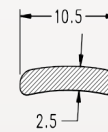
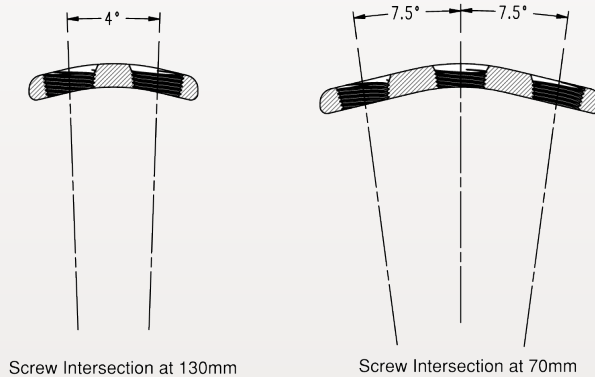
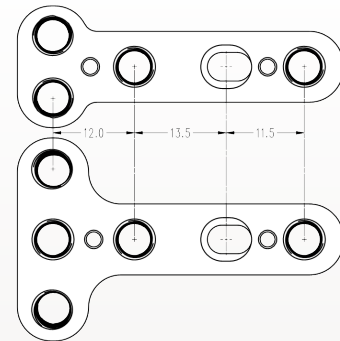
LOCKING COMPRESSION PLATES

Item Number	Description	Holes	Length (mm)
00-1005-2204	2.7mm Reconstruction Plate	4	44
00-1005-2208	2.7mm Reconstruction Plate	6	80
00-1005-3204	3.5mm Reconstruction Plate	4	53
00-1005-3206	3.5mm Reconstruction Plate	6	76
00-1005-3208	3.5mm Reconstruction Plate	8	99



T-PLATES

Item Number	Description	Holes	Length (mm)
00-1005-3303	3.5mm Locking T-Plate, 2 Hole Head	3	48
00-1005-3305	3.5mm Locking T-Plate, 2 Hole Head	5	71



WASHER & PINS

Item Number	Description
00-1030-000	Bone Screw Washer (Ø 4.0)
00-1005-0001	1.25mm x150mm Wire, Smooth
00-1005-0002	1.6mm x 150mm Wire, Smooth
00-1005-0003	2.0mm x 150mm Wire, Smooth

SCREWS

2.7MM SCREWS

2.7mm Cortical Screw, T10 Hexalobe, Self Tapping

Item Number	Size
00-1005-2508	8
00-1005-2510	10
00-1005-2512	12
00-1005-2514	14
00-1005-2516	16
00-1005-2518	18
00-1005-2520	20
00-1005-2522	22
00-1005-2524	24
00-1005-2526	26
00-1005-2528	28
00-1005-2530	30

2.7mm Locking Screw, T10 Hexalobe, Self Tapping

Item Number	Size
00-1005-2608	8
00-1005-2610	10
00-1005-2612	12
00-1005-2614	14
00-1005-2616	16
00-1005-2618	18
00-1005-2620	20
00-1005-2622	22
00-1005-2624	24
00-1005-2626	26
00-1005-2528	28
00-1005-2530	30

3.5MM SCREWS

3.5mm Cortical Screw, T15 Hexalobe, Self Tapping

Item Number	Size
00-0903-2510	10
00-0903-2512	12
00-0903-2514	14
00-0903-2516	16
00-0903-2518	18
00-0903-2520	20
00-0903-2522	22
00-0903-2524	24
00-0903-2526	26
00-0903-2528	28
00-0903-2530	30
00-0903-2535	35
00-0903-2540	40
00-0903-2545	45
00-0903-2550	50
00-0903-2555	55
00-0903-2560	60

3.5mm Locking Screw, T15 Hexalobe, Self Tapping

Item Number	Size
00-0903-2610	10
00-0903-2612	12
00-0903-2614	14
00-0903-2616	16
00-0903-2618	18
00-0903-2620	20
00-0903-2622	22
00-0903-2624	24
00-0903-2626	26
00-0903-2628	28
00-0903-2630	30
00-0903-2635	35
00-0903-2640	40
00-0903-2645	45
00-0903-2650	50
00-0903-2655	55
00-0903-2660	60

4.0MM CANNULATED SCREWS

4.0mm Cannulated Cancellous Screw T15 Hexalobe, Full Thread

Item Number	Size
00-1005-4010	10
00-1005-4012	12
00-1005-4014	14
00-1005-4016	16
00-1005-4018	18
00-1005-4020	20
00-1005-4022	22
00-1005-4024	24
00-1005-4026	26
00-1005-4028	28
00-1005-4030	30
00-1005-4035	35
00-1005-4040	40
00-1005-4045	45
00-1005-4050	50
00-1005-4055	55
00-1005-4060	60

4.0mm Cannulated Cancellous Screw T15 Hexalobe, Partial Thread

Item Number	Size
-	-
-	-
-	-
00-1005-4216	16
00-1005-4218	18
00-1005-4220	20
00-1005-4222	22
00-1005-4224	24
00-1005-4226	26
00-1005-4228	28
00-1005-4230	30
00-1005-4235	35
00-1005-4240	40
00-1005-4245	45
00-1005-4250	50
00-1005-4255	55
00-1005-4260	60

INSTRUMENTS

GUIDES

Item Number	Description
01-1005-0011	2.0mm Threaded Drill Guide
01-1200-0067	2.5mm Threaded Drill Guide
01-1005-0012	Universal Drill Guide (2.0/2.7)
01-1005-0013	Universal Drill Guide (2.5/3.5)
gS 86.2507	2.0 Drill Guide / Sleeve Parallel
01-1030-013	2.7/1.25 Drill Guide
gS 86.2503	Double Drill Sleeve, 2.7/2.0mm
gS 86.2504	Double Drill Sleeve, 3.5/2.5mm

DRILL BITS

Item Number	Description
01-1005-0003	2.0mm Drill Bit
01-1005-0004	2.0mm Calibrated Drill Bit
01-1050-0002	2.5mm Drill Bit
01-1050-0032	2.5mm Calibrated Drill Bit
01-1005-0005	2.7mm Drill Bit
01-1005-0006	3.5mm Drill Bit
01-1030-003	AO Cannulated Drill 2.7mm

TAPS & COUNTERSINK

Item Number	Description
01-1005-0007	2.7mm Cortical Tap
01-1050-0006	3.5mm Cortical Tap
01-1030-005	AO Cannulated Tap 4.0
01-1005-0008	Cannulated Countersink

MEASURING DEVICES

Item Number	Description
01-1005-0015	2.7 Depth Gauge (Yellow), 10-60mm
01-1200-0080	3.5 Depth Gauge (Blue), 10-60mm
01-0999-2002	Scale, 10-60mm
01-1005-0016	Direct Measuring Device

DRIVERS

Item Number	Description
01-1005-0037	T10 Retaining Driver, Short
01-0903-0005	T15 Retaining Driver, Short
01-1005-0032	T15 Cannulated Driver, Short (Dia. 1.25mm)

MISCELLANEOUS INSTRUMENTS

Item Number	Description
01-0907-0022	2.0mm x 150mm Guide Wire, threaded
01-1005-0017	2.7mm Threaded Plate Holder
01-1005-0018	3.5mm Threaded Plate Holder
01-1005-0020	Plate Fixation Pin
01-1005-0022	Bone Scoop
01-1005-0023	Bending Iron
01-1005-0026	2.7mm Bending Template
01-1005-0027	3.5mm Bending Template
01-1005-0029	2.5mm x 150mm Guide Wire, threaded
01-1005-0031	Bending Iron for Wires
01-1010-001	Mini T-Handle, AO QC
01-1030-001	Mini Inline Ratchet
01-1030-006	1.25mm Guide Wire
01-1030-007	Screw Forceps
01-1030-008	Holding Clip
01-1030-010	Cleaning Stylet
01-1030-011	1.35mm Cleaning Brush
01-1030-015	Screw Removal Tool
01-1050-0013	Sharp Hook
01-1050-0016	Toothed Bone Reduction Forceps
01-1050-0017	Bone Reduction Forceps with Points, Narrow
01-1050-0018	Mini Hohmann Retractor
01-1050-0019	Hohmann Retractor
01-1050-0020	Periosteal Elevator, Sharp
01-1050-0022	Bending Pliers
gS 82.1020	K-Wire Bender
gS 46.1900	Verbrugge Forceps, 6"
gS 46.1920	Verbrugge Forceps 7 1/2"

TRAY COMPONENTS

Item Number	Description
01-0999-1000	OrthoPediatrics Lid
01-1005-1007	PediFrag Fragment System 2.7/3.5 - Screw Caddy
01-1005-1008	PediFrag Fragment System 2.7/3.5 - Screw Caddy Lid
01-1005-1009	PediFrag Fragment System 2.7/3.5 - 2.7 Tray
01-1005-1010	PediFrag Fragment System 2.7/3.5 - 3.5 Tray
01-1005-1011	PediFrag Fragment System 2.7/3.5 - Base

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: **This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.**

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document is of general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

The information contained in this document was gathered and compiled by medical experts and qualified OrthoPediatrics employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of the understanding of the information used and presented. OrthoPediatrics does not practice medicine and does not recommend any particular orthopedic implant or surgical technique for use on a specific patient. The surgeon is responsible for determining the appropriate device(s) and technique(s) for each individual patient.

OrthoPediatrics does not assume any liability, however, for the timeliness, accuracy, completeness or quality of the information and excludes any liability for tangible or intangible losses that may be caused by the use of this information.

Not for distribution in France

Instructions For Use (IFU), cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatrics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

OrthoPediatrics, ArmorLink, Jiminy, PediFlex, PediFrag, PediLoc, PediNail, PediPlates, PLEO, RESPONSE, Scwire, ShieldLoc, TorqLoc, and the OP and Pedi logos are trademarks of OrthoPediatrics Corp.

OrthoPediatrics is a registered trademark in Brazil, S.Korea, and the U.S.A. Jiminy is a registered trademark in the European Union and the U.S.A. PediLoc and PediPlates are registered trademarks in Chile and the U.S.A. The OP logo is a registered trademark in Colombia, European Union, Japan, and the U.S.A. The Pedi logo is a registered trademark in Argentina, Australia, Brazil, Chile, Colombia, European Union, Israel, Mexico, New Zealand, S.Korea, Taiwan, Turkey, and the U.S.A. Scwire is a registered trademark in the U.S.A.

